

Commonwealth of Massachusetts
DEPARTMENT OF HOUSING &
COMMUNITY DEVELOPMENT

Charles D. Baker, Governor ♦ Karyn E. Polito, Lt. Governor ♦ Jennifer D. Maddox, Undersecretary

To: EA, Individual Shelter, Youth Shelter, and Domestic Violence Shelter Providers
From: Alvina Brevard, Associate Director, Department of Housing and Community Development
Date: December 9, 2020
Subject: Guidance for Shelter regarding COVID-19, Testing (Including Accessing Abbott BinaxNOW Rapid Tests) and Positive Tests in Shelter

Summary: This document compiles COVID-related guidance to homeless shelters in one location. This document is subject to change based on public health guidance.

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I. Interpreting Recent Executive Orders and Advisories

- a. Governor Baker's COVID-19 Order 55, effective as of Nov 6th, requires that all persons above the age of 5 wear a mask or cloth facial covering in indoor and outdoor public places, with some exceptions due to medical or disabling conditions. Family shelters are not clearly designated as public places and therefore there is no clear answer as to whether mask usage in shelter common spaces would fall under the executive order. Nevertheless, shelters can and should strongly encourage guests to wear masks any time they are outside of their rooms, regularly wash hands, and maintain social distancing as much as is feasible.
- b. On November 2, 2020, the Department of Public Health issued a Stay-At-Home Advisory for all residents of Massachusetts. The advisory went into effect as of Nov 6th. To

comply with the advisory, between the hours of 10pm to 5am, persons must only leave home for essential needs and practice social distancing; not gather with those outside of their household; avoid touching surfaces frequently touched by others if persons go outside for fresh air. While advisories are not legal mandates, families in EA shelters should be made aware of the advisory and be encouraged to abide by the recommendations.

II. DHCD Support Regarding Mask Compliance and Curfew

- a. DHCD strongly recommends that masks be worn by all persons above the age of 2 in all common spaces of the shelter.
- b. DHCD is discouraging the use of the EA Non-Compliance system as a means to enforce mask wearing in family shelters, in favor of more effective and trauma-informed practices to support families who struggle with mask compliance. Interventions may include consultations with DHCD, referrals to DPH/FOR Families, and transfers. However, NonCompliances shall be considered and may be expedited when the refusal to wear a mask is combined with other aggressive behavior that meets the criteria under serious incidents/health and safety and/or other rule violations.
 - i. [Postable flyers regarding mask wearing can be found here.](#)
- c. DHCD strongly recommends that families abide by the Department of Public Health Advisory regarding the 10pm curfew. Curfew Violations generally are not considered a priority issue area for the purposes of substantiating NonCompliances. However, NonCompliances shall be considered and potentially expedited when combined with other priority rule violations and noncompliance priorities.
- d. DHCD can assist in securing additional PPE for staff and families if a shelter program is not able to obtain specific items. Face shields and additional PPE are encouraged for shelter staff.

III. Offsite Testing

- a. Stop the Spread: Free, symptomatic or asymptomatic testing across the state at specific testing locations

All guests and staff are encouraged to make use of Stop the Spread testing locations, which offer free testing to any Massachusetts resident. These sites are located across the state, and do not require the individual to have insurance, be symptomatic, or even be exposed.

Stop the Spread testing sites are listed here: <https://www.mass.gov/info-details/stop-the-spread>

- b. Other Testing Sites: May require insurance, payment, or other risk factors

In addition to Stop the Spread sites, there are private and publicly run sites across the Commonwealth. These sites may have more restrictions than Stop the Spread sites, including insurance or payment requirement, a requirement that the individual be symptomatic or have a doctor's order, or a requirement that the individual be at risk for contracting COVID. Some payment requirements may be substantial, so providers are advised to check requirements before directing families to a testing site.

Insurance companies in Massachusetts are required to cover COVID-19 testing without copays for all individuals who are symptomatic or a close contact.

Statewide testing sites are listed on this map:

<https://memamaps.maps.arcgis.com/apps/webappviewer/index.html?id=eba3f0395451430b9f631cb095febf13>

IV. Surveillance Testing

The Commonwealth is unable to coordinate and pay for surveillance testing (regular testing of a small number of asymptomatic shelter guests) in EA and individual shelters at this time.

However, shelter providers may:

- a. Contact their local board of health, and see what options may exist for surveillance testing that is facilitated at the local level.
- b. Use non-DHCD funds to purchase testing resources directly to conduct surveillance testing.
 - i. Surveillance testing can help find inapparent cases of COVID and prevent larger outbreaks. The testing regimen should be done under the guidance of local public health or DPH epidemiology.
 - ii. DPH has compiled a list of lower cost testing resources for municipalities that providers could use directly as well: <https://www.mass.gov/info-details/covid-19-testing-guidance#guidance-for-municipal-leaders>
 - iii. These costs are not reimbursable through DHCD contracts.

V. Abbott BinaxNOW Rapid Tests

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DOD) recently announced an initiative to deliver 150 million Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 rapid diagnostic tests to schools and other strategic environments. Massachusetts will receive up to 2 million tests for use in priority settings, including but not limited to homeless shelter settings. The Massachusetts Department of Housing and Community Development (DHCD) in collaboration with the Massachusetts Department of Public Health (DPH) will provide the first phase of these tests, and participating shelters will receive the test kits at no cost. In most cases, participating shelters will be able to administer the test using existing staff resources. Personnel performing the tests will need training; please see “Staff Training Requirements” below.

This section of the memo provides participating shelter agencies with an overview of the use of Abbott BinaxNOW test kits and information regarding the documentation, reporting requirements, and protocols required prior to and after receiving test kits. The last part of this section includes a Readiness Review Checklist for completion by the participating shelter agency as a prerequisite to request for distribution of Abbott BinaxNOW test kits.

Use of Abbott BinaxNOW test in Shelters:

The Abbott BinaxNOW test is a rapid antigen test. Rapid antigen tests perform best when the person tests in early stages of infection (when the person is within 7 days of the onset of symptoms) with SARS-CoV-2, which is when the viral load is generally highest.

The Abbott BinaxNOW test is only to be used to test shelter participants and staff with symptoms of an illness consistent with COVID-19 OR who may have been in contact with a person who tested positive or any member of their household. It is not for use as broad scale asymptomatic or “surveillance” testing in shelters.

When a shelter participant or staff member appears to have a medical need other than a clearly identifiable physical injury (e.g., broken finger), the shelter should respond using the following protocol:

1. Shelter participants and staff with severe or life-threatening symptoms: Call 911 immediately
2. Shelter participants and staff with the following symptoms of an illness consistent with COVID-19 should be considered for testing using the Abbott BinaxNOW test:
 - Fever (100.0° Fahrenheit or higher) or chills
 - Cough
 - Difficulty breathing or shortness of breath
 - New loss of taste or smell
 - Sore throat
 - Headache
 - Muscle aches or body aches
 - Nausea or vomiting
 - Fatigue
 - Nasal congestion or runny nose
3. Those who test positive should follow the COVID positive guidance in Sections VI and VII of this memo and their primary care provider should be notified of the positive test.
4. Those who test negative should be informed of the test results and follow up with their healthcare provider, as needed.
 - If there is strong clinical suspicion of COVID-19, best practice is to follow up with a PCR test as soon as possible, including:
 - i. If a healthcare professional identifies significant COVID-19 symptoms, (i.e., fever, cough) and/or
 - ii. There was known **close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for a COVID-positive individual)**

- If symptoms persist, individual should be re-tested after 1-3 days using the Abbott BinaxNOW test.

PCR Testing:

Given the superior accuracy of PCR testing versus antigen testing, the result of a PCR test taken within 2 days of an antigen test will “override” the result of the antigen test. Consequently, a PCR test result (rather than an Abbott BinaxNOW antigen test result) should determine the proper protocol for the shelter participant or staff if taken within 2 days of an antigen test result.

Disposal of Used Tests

All staff administering the tests should follow the instructions provided on the Abbott BinaxNOW package insert regarding specimen collection, handling, transport and storage as is detailed here: <https://www.fda.gov/media/141570/download>

In accordance with the BinaxNOW COVID-19 Ag Card test’s instructions for use (IFU), test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). The IFU states to ensure that the test components (Antigen card and buffer) are at room temperature (59 and 86°F) during performance of the test. DPH requires the room temperature to be recorded upon test administration. Data obtained by DPH indicates that the test’s accuracy is significantly reduced when used outside of this temperature range.

See the Abbott BinaxNOW package insert for instructions on its proper use. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Shelters should have a plan on how they will dispose of the biohazardous waste prior to implementation of the testing program. It is recommended that shelters work with their facilities managers and if necessary, their local board of health to determine an appropriate process for the removal of waste.

Requirements:

All participating shelter agencies must complete all six of the following requirements in order to receive approval from DHCD for their distribution of Abbott BinaxNOW test kits.

- ✓ Obtain an approved CLIA certificate of waiver
- ✓ Secure a signed physician order for testing
- ✓ Confirm ability to maintain an adequate supply of PPE
- ✓ Ensure all testing staff meet training requirements
- ✓ Review consent forms
- ✓ Verify ability to complete DPH reporting requirements

Shelter agencies should expect a supplementary memo with information on consent forms and DPH reporting requirements; use of the NAVICA app referenced in the BinaxNOW materials is not necessary. Reporting will be done through another system provided by DPH.

The testing should be performed at room temperature (59-86 deg F). This is important, as the performance of the test can deteriorate at lower or higher temperatures.

Distribution process:

Each participating shelter agency must complete the [Readiness Review Checklist available here](#) which certifies that they have completed all the requirements.

After the checklist is completed and submitted, DHCD will follow up with shelters directly. If all requirements are satisfied, the shelter agency will submit an order form directly to DPH to schedule a delivery of test kits.

Obtaining a CLIA certificate:

Before receiving and administering tests, shelters must have a “Clinical Laboratory Improvement Amendments (“CLIA”) Certificate of Waiver.

Please find the application for a CLIA Certificate (CMS Form 116) here:

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

You need one CLIA Certificate of waiver for your shelter agency, regardless of how many shelter sites you operate, if CLIA multiple site criteria are met.

For your convenience, we are sharing some information that may help you fill out your CLIA application if your facility does not already have a CLIA Certificate of Waiver or other appropriate CLIA certificate:

- In section I, please select “Initial Application” and under “Other Changes (Specify)” fill in “COVID 19” to alert the Clinical Laboratory Program that your application is a part of this distribution effort. The Facility Address must be the physical address of a location that is performing testing even if you are applying for multiple site designation. DHCD suggests that the Director should be an individual who is positioned to ensure compliance with CLIA regulations, like your organization’s Executive Director.
- In section II, please select “Certificate of Waiver” if you will be performing only the Abbott BinaxNOW COVID-19 Ag Card test or other CLIA-waived tests.
- In section III, please select “29- Other, and specify Homeless Shelter”
- In section IV, select the appropriate hours the shelter is open.
- In section V, please select “No” if you have one single shelter location, please select “Yes” if you are applying as a shelter agency and have more than one shelter location.
 - In #1 in section V, please select “No”
 - In #2 in section V, please select “Yes” enter the number of shelter locations.
 - In #3 in section V, please select “No.”
 - Please note that only one of the multiple site criteria may be selected.

- In section VI, please enter “Abbott BinaxNOW COVID-19 Ag Card Test” and provide the Estimated Total Annual Test Volume (2 x the total number of shelter guests); however, DPH is still determining the number of tests available per shelter agency. If additional CLIA-waived tests will be performed, the test and specific test system information should be included in this section.
- In Section VII, please leave blank.
- In Section VIII, please leave blank.
- In Section IX, enter the type of organization you are.
- In Section X, enter information about additional laboratories, if any, and have the Executive Director, CEO, or equivalent sign the form. If no additional laboratories, please leave blank (most shelters will leave this section blank).

Please send the completed applications to The Clinical Laboratory Program at CLIALab@mass.gov. If you have any questions, you may contact the Clinical Laboratory Program at (617) 660-5385.

A resource you may find helpful is this Quick Start Guide from CMS:

<https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>

Securing a signed physician order:

The Abbott BinaxNOW test must be ordered by a physician. The participating shelter agency must have a standing physician order in place prior to requesting test kits from DPH. Shelter agencies may obtain a standing order from a local board of health medical director.

DPH has drafted a model standing order which can be used by shelters to request a standing order a local board of health medical director. The model standing order can be found attached in Appendix 1.

Maintaining an adequate supply of PPE:

Shelter Agencies should acquire their own PPE, and alert DHCD if unable to obtain specific items. All staff administering Abbott BinaxNOW test kits must wear appropriate personal protective equipment (PPE) when running each test and handling patient specimens. For personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- N95 mask or higher-level respirator (a surgical mask can be used only if an N95 is not available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Staff administering tests must change gloves between handling of specimens suspected of COVID-19. Refer to [DPH Comprehensive PPE Guidance](#) or contact your local board of health for further information regarding the proper use of PPE.

Shelter Agencies must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

Ensuring all staff complete training requirements

All staff administering Abbott BinaxNOW test kits within a sheltering agency must complete the Abbott BinaxNOW training modules below. The Abbott BinaxNOW training modules found [here](#).

The Abbott BinaxNOW training modules include:

Module 1: Getting Started

Module 2: Quality Control

Module 3: Specimen Collection and Handling

Module 4: Patient (Individual) Test

These modules provide a detailed step-by-step guide to the test process. Modules 1-4 must be completed in their entirety prior to staff performing test on individuals.

It is the responsibility of the participating shelter agency to ensure that all the staff administering tests have completed the necessary training requirements. Staff administering tests must watch the Abbott BinaxNOW video training modules as part of their attestation prior to ordering tests.

Additionally, further information about the proper use of the Abbott BinaxNOW test kits can be found on the package insert and [here](#). This includes information regarding specimen collection, handling, transportation, and storage.

Staff who have questions or concerns about the administration of the test can utilize these direct links to Abbott support: 800-257-9525 8:00 am – 8:00 pm Monday through Friday or ts.scr@abbott.com.

Obtaining consent:

DHCD and DPH will provide further information on the consent and authorization for the administration of Abbott BinaxNOW test kits. Any individual receiving a BinaxNOW test must consent to the administration of the test as well as the information sharing required to report results to the Massachusetts DPH.

This consent process, which will include options for electronic or paper consent forms, will include obtaining signature from shelter participants prior to administering the tests.

Verifying ability to complete all reporting requirements

Shelter agencies participating in this initiative must report all test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) AND continue to report ALL positive test results to DHCD weekly by 5:00pm on Fridays.

- EA shelter reports sent to: Virginia.K.Griffin@mass.gov by 5 pm every Friday
- Individual shelter reports sent to: Amber.Noyes@mass.gov by 5 pm every Friday

Additional information about how participating shelter agencies will report test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences to be provided in a supplementary memo prior to the distribution of test kits.

VI. Positive Tests in EA

If an EA family member or onsite staff member tests positive, immediately:

- a. Isolate the person or household in a location away from others, or send the staff person home. If it is necessary for the individual who tested positive to be around other persons for any length of time, require them to wear a mask.
- b. If the individual has difficulty breathing or other life-threatening symptoms, call 911.
- c. Contact Virginia Griffin, Barbara Duffy and your contract manager, and identify whether the family can safely isolate in their current placement or should be moved to another unit with the same provider or, if needed, a nearby EA provider.
- d. If the individual or staff person lived/worked in a congregate, or if staff members have had close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for) the COVID-positive individual, pursue the following options:
 - a. If Abbott BinaxNOW tests are available and the shelter is approved for Abbott BinaxNOW use, test all individuals who may have been in contact with the person who tested positive or any member of their household using Abbott BinaxNOW tests.
 - b. If Abbott BinaxNOW tests are not available, coordinate with the local board of health to see whether they can test congregate residents/staff using PCR tests.
 - c. If Abbott Rapid Tests are not available, the local board of health cannot test residents, *and* there evidence of virus spread within the congregate site (i.e., 2 or more cases in a facility within 2 weeks), please call the MA Department of Public Health at 617-983-6800 to be screened by the on-call epidemiologist at DPH. DPH will deploy mobile units as necessary.
- e. If the individual was in a scattered site, recommend the household remain in their apartment and facilitate food and other deliveries as needed. Contact the family daily, if not more regularly, to inquire about their status and needs.

VII. Positive Tests in Individual Shelters

If a shelter resident/staff tests positive, immediately:

- a. Isolate the person in a room or location away from others. If it is necessary for the individual who tested positive to be around other persons for any length of time, require them to wear a mask.
- b. If the individual has difficulty breathing or other life-threatening symptoms, call 911.
- c. If the individual does not appear to have life-threatening symptoms, call 617-367-5150 between the hours of 7am and 7pm for access to an isolation hotel. The Massachusetts Emergency

Management Agency (MEMA) operates isolation hotel(s) across the Commonwealth for COVID-positive individuals who do not have homes. Transportation to/from the isolation hotel is provided free of charge. As of 12/9/20, there are three isolation hotels - in Pittsfield, Everett and Taunton - which are available to individuals statewide; MEMA will add additional hotels as demand requires.

- d. If the individual or staff person lived/worked in a congregate, or if staff members have had close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for) with the COVID-positive individual, pursue the following options:
 - i. If Abbott BinaxNOW tests are available and the shelter is approved for Abbott BinaxNOW use, test all individuals who may have been in contact with the person who tested positive or any member of their household using Abbott BinaxNOW tests.
 - ii. If Abbott BinaxNOW tests are not available, coordinate with the local board of health to see whether they can test congregate residents/staff using PCR tests.
 - iii. If Abbott Rapid Tests are not available, the local board of health cannot test residents, *and* there evidence of virus spread within the congregate site (i.e., 2 or more cases in a facility within 2 weeks), please call the MA Department of Public Health at 617-983-6800 to be screened by the on-call epidemiologist at DPH. DPH will deploy mobile units as necessary.

VIII. Prevention

- A. Staff and guests can help stop COVID spread. Specifically:
 - a. **Wear a mask**, any time you are interacting with people outside of your household.
 - b. **Wash your hands often** with soap and warm water for at least 20 seconds, and/or sanitize hands with sanitizing solutions that are at least 60% alcohol.
 - c. **Cover your mouth when you cough or sneeze. Use a tissue or your inner elbow, not your hands.**
 - d. **Avoid touching** your eyes, nose and mouth.
 - e. **Increased housekeeping practices**, please refer to the Center on Disease Control's Effective Cleaning and Disinfecting Recommendations: <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/cleaning-disinfection.html>
 - f. **Reduce sharing** of dishes, drinking glasses, cups, eating utensils, towels, bedding, or other items with other people. Wash items thoroughly with soap and hot water. Consider disposable paper and plastic products.
 - g. **Increase social distancing** as much as is feasible – consider staggering meals or asking residents to eat in their rooms; shifting the structure of house meetings to smaller gatherings; increase use of flyers, bulletin boards, email, texting, and phone calls to communicate instead of face to face contact.
 - h. **Isolate if you are sick** and avoid close contact with others.
- B. Please post the following notice in a conspicuous location in all shelter facilities (EA and individual)

- a. Required: <https://www.mass.gov/doc/wear-a-mask-or-face-covering/download>; additional languages are available here: <https://www.mass.gov/info-details/covid-19-printable-fact-sheets#wear-a-mask->
- b. Optional Posters: <https://www.mass.gov/info-details/covid-19-printable-fact-sheets>

Appendix 1: Model Standing Order

Massachusetts Department of Public Health

SAMPLE STANDING ORDER

Abbott BinaxNOW Rapid Point of Care COVID-19

These sample standing orders are current as of December 2020. They should be reviewed carefully against the most current recommendations from the Department of Housing and Community Development (DHCD) and the Department of Public Health (DPH).

Purpose: To facilitate the rapid identification SARS-CoV-2 using the rapid point of care Abbott COVID-19 Ag Card test, this standing order is issued pursuant to my authority as a licensed physician in Massachusetts to order the examination of any specimen derived from the human body, pursuant to G.L. c. 112D, section 8(7). This standing order allows individuals to undergo testing for SARS-CoV-2, the virus that causes COVID-19, subject to the terms and requirements outlined below:

1. Ensure the test is administered in a qualified point-of-care setting by trained personnel

The EUA for the Abbott BinaxNOW COVID-19 Ag card test allows for use in point-of-care settings that are qualified to have the test performed and are operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Personnel must have completed training to perform the sample collection and testing.

2. Temperature requirements for BinaxNOW COVID-19 Ag Card tests

In accordance with the BinaxNOW COVID-19 Ag Card test's instructions for use (IFU), test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). The IFU states to ensure that the test components (Antigen card and buffer) are at room temperature (59 and 86°F) during performance of the test. DPH requires the room temperature to be recorded upon test administration. Data obtained by DPH indicates that the test's accuracy is significantly reduced when used outside of this temperature range.

3. Instruct staff collecting the test to follow infection control precautions when handling clinical specimens.

Precautions when caring for or obtaining samples from an individual suspected to be COVID-19 positive include contact and droplet precautions with hand hygiene and the use of PPE that includes gown, gloves, N95 filtering facepiece respirator or higher (use a facemask if a respirator is not available), and eye protection such as goggles or faceshield. Guidance for prioritizing and optimizing use of Personal Protective Equipment can be found [here](#).

4. Assess individuals for their eligibility to be tested and the protocol to be followed upon completion of the test.

Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest.

The Abbott BinaxNOW test should **not** be used for broad scale asymptomatic testing in shelters.

When a shelter participant or staff member appears to have a medical need other than a clearly identifiable physical injury (e.g., broken finger), the shelter should respond using the following protocol:

- A. Shelter participants and staff with severe or life-threatening symptoms: Call 911 immediately
- B. Shelter participants and staff **with the following symptoms of an illness consistent with COVID-19** should be considered for testing using the Abbott BinaxNOW test:

<u>Symptoms consistent with COVID-19</u>
<ul style="list-style-type: none">• Fever (100.0° Fahrenheit or higher), chills, or shaking chills• Cough• Difficulty breathing or shortness of breath• New loss of taste or smell• Sore throat• Headache• Muscle aches or body aches• Nausea, vomiting, or diarrhea• Fatigue• Nasal congestion or runny nose

Those who test positive should follow the COVID positive guidance in Sections VI and VII of the memo guidance provided by DHCD to shelters.

Those who test negative should be informed of the test results and follow up with their healthcare provider; if there is strong clinical suspicion of COVID-19, best practice is to follow up with a PCR test as soon as possible. If a healthcare professional identifies significant COVID-19 symptoms, (i.e., fever,

cough), or if there was close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for a COVID-positive individual), a PCR test is recommended to rule out COVID-19.

If symptoms persist, individual should be re-tested after 1-3 days using the Abbott BinaxNOW test.

5. Check for appropriate authorizations to perform testing.

Ensure consent has been granted prior to administering a test. Consent must be given by a parent/guardian if appropriate. DHCD and DPH will release consent and reporting guidance that must be utilized when administering Abbott BinaxNOW COVID-19 Ag Card test kits.

6. Perform positive and negative control tests for each new box opened

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. BinaxNOW COVID-19 Ag Card kits contain a Positive Control Swab (i.e., a swab which will trigger a positive result, but does not contain any infectious virus) and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new box received, and once for each untrained operator.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support (1-800-257-9525 or ts.scr@abbott.com) during normal business hours before testing patient specimens.

7. Prepare and administer Abbott BinaxNOW test.

Prepare and administer the Abbott BinaxNOW test according to the package insert. If instructions in the package insert contradict the instructions below, the instructions on the package insert should be followed.

A. NASAL SWAB

Only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).

Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

B. SPECIMEN TRANSPORT and STORAGE

Do not return the nasal swab to the original paper packaging. For best performance, direct nasal

swabs should be tested as soon as possible after collection.

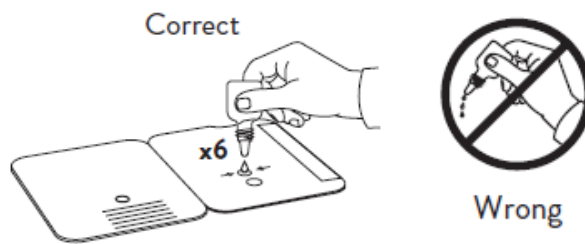
If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed.

If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

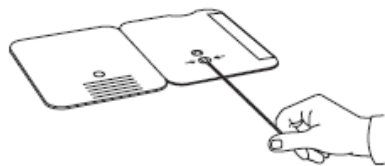
C. TEST PROCEDURE: Procedure for Patient Specimens

Open the test card just prior to use, lay it flat, and perform assay as follows. The test card must be flat when performing testing, do not perform testing with the test card in any other position.

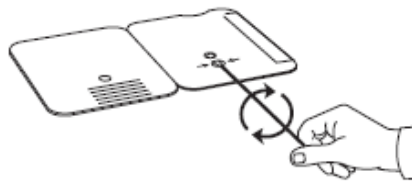
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.



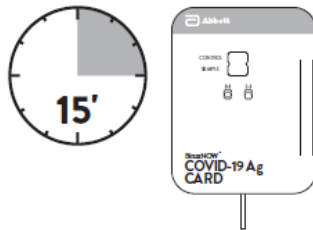
3. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



Note: False negative results can occur if the sample swab is not rotated (twirled)

prior to closing the card.

4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.



Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

8. Document test administration and provide appropriate notice

Every effort should be made to inform the individual's primary care provider of the result of the test.

Shelters must report test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) through the Project Beacon system established by DPH.

Standing Orders Authorization

This policy and procedure shall remain in effect for all residents and staff of _____
name of shelter

until rescinded or until _____
date

Healthcare Provider's signature _____ Signature date _____ Effective date _____

Print Healthcare Provider's Name: _____